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10/591,203	06/22/2007	Robert J. Maier	31725-200815	7327

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01/06/2010

EXAMINER

DEVI, SARVAMANGALA J N

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,203	Applicant(s) MAIER ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 091009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 083106 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>083106</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendments

- 1) Acknowledgment is made of Applicants' preliminary amendments filed 09/10/09, 08/31/06 and 04/22/09.

Election

- 2) Acknowledgment is made of Applicants' election filed 04/22/09 in response to the written lack of unity and species election requirement mailed 03/25/09. Applicants have elected invention I, claims 1-10, without traverse, and the *S. typhimurium* bacterium species.

Status of Claims

- 3) Claim 9 has been cancelled via the amendment filed 09/10/09.
New claims 18-21 have been added via the amendment filed 09/10/09.
Claims 1, 5, 6 and 11 have been amended via the amendment filed 09/10/09.
Claims 1-8 and 10-21 are pending.
Claims 11-17 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.
Claims 1-8, 10 and 18-21 are under prosecution. A First Action on the Merits is issued for these claims.

Information Disclosure Statement

- 4) Acknowledgment is made of Applicants' information disclosure statement filed 08/31/06. The information referred to therein has been considered and a signed copy of the same is attached to this Office Action.

Sequence Listing

- 5) Acknowledgment is made of Applicants' sequence listing, which has been entered on 10/16/08.

Priority

- 6) This application is a national stage 371 application of PCT/US2005/006638, filed 02/28/05, which claims priority to the U.S. provisional application 605493066, filed 03/02/2004 and 60604846 filed 08/26/04.

Objection(s) to Specification

7) The instant specification is objected to for the following reason:

(A) The amendment made to page 1 of the specification requests replacement of the original first paragraph with a new paragraph without showing the changes made therein via markings as required under 37 C.F.R 1.121. Replacement paragraphs must include markings to show the changes.

(B) The use of a trademark recitation in the instant specification has been noted. For example, see line 22 of page 16 for 'TritonX-100' and line 12 of page 36 for 'Supermix'. All trademark recitations should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix 1. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

8) Claim 21 is rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological material is (1) known and readily available to the public; (2) reproducible from the written description, e.g. sequenced; or (3) deposited.

Claim 21 is directed to a composition comprising the *S. typhimurium* strain, JSG 321, deposited with the ATCC and assigned the deposit accession number PTA-6556. It is apparent that this strain is required to practice the claimed invention. As a required element, the strain must be known and be readily available to the public, or obtainable by a reproducible method set forth in the specification, or otherwise be readily available to the public. If it is not so obtainable or available, the enablement requirement of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the *S. typhimurium* strain, JSG 321. From the instant specification, it appears that the strain has been deposited at a recognized depository, ATCC. However, the required statement by a registered attorney of record or an Assignee who has authority and control over the conditions of the deposit, stating that the deposit has been accepted under the provisions of

the Budapest Treaty, that **all** restrictions upon public access to the deposit will be *irrevocably removed* upon the grant of a patent on this application, has not been submitted. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each state. Further, the statement should identify the deposited strain(s) by its depository accession number, establish that the deposited strain(s) is the same as the one described in the specification, and establish that the deposited strain(s) was in Applicants' possession at the time of filing. Applicants are encouraged to submit the notice of acceptance of the strain by the depository to establish that the deposited strain is the same as the one described in the specification.

Applicants' attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 C.F.R § 1.801-1.809 for further information concerning deposit practice.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 2-5, 7, 8, 10 and 18-21 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 2-4 are indefinite and confusing in the limitation 'The isolated bacterium of claim 1 wherein *the strain* comprises a mutation' [Emphasis added]. These claims depend directly or indirectly from claim 1, wherein the only 'strain' recited is 'a wild type strain'. It is unclear whether the mutation is present in the wild type strain or the isolated bacterium.

(b) Claim 7 is indefinite because it lacks proper antecedent basis in the limitation: 'an isolated bacterium of claim 3'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the isolated bacterium of claim 3--.

(c) Claim 3 depends from claim 2. Claims 2 and 3 are indefinite, inconsistent and confusing in the limitations: 'the encoded NiFe hydrogenase enzyme..' and 'a functional NiFe hydrogenase protein' respectively. Is the latter different from the former?

(d) Claim 3 is further indefinite, confusing and appears to have improper antecedent basis in the limitation: 'the NiFe hydrogenase genes present in the genome of the strain the

mutations'. Claim 3 depends from claim 2, which includes the limitation of 'a mutation of a NiFe hydrogenase gene', but not more than one NiFe hydrogenase gene and more than one mutation.

(e) Claim 18 is indefinite, confusing and appears to have improper antecedent basis in the limitation: 'the NiFe hydrogenase genes'. Claim 18 depends from claim 2, which includes the limitation of 'a mutation of a NiFe hydrogenase gene', but not more than one NiFe hydrogenase gene and more than one mutation.

(f) Claim 19 is further vague and indefinite in the limitation 'STM 3147, STM 1538 and STM 1786', because it is unclear what structure is encompassed in this limitation. Do these represent specific nucleotides, any gene regions, or the NiFe hydrogenase gene fragments or subunits?

(g) Claim 20 is indefinite in the limitation: 'NiFe hydrogenase genes expression of the NiFe hydrogenase gene product'. Does it mean that mutation in pleural NiFe hydrogenase genes prevents expression of one NiFe hydrogenase gene product?

(h) Claim 21 is indefinite in that the claim includes limitations within parentheses (see line 3) and raises an indefiniteness issue as to whether or not the recitation is included, excluded, or optional.

(i) Claims 3, 5, 18 and 19, which depend from claim 2, claims 8 and 10 which depend from claim 7, and claim 21, which depend from claim 20, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12) Claims 1-7, 18 and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986).

Sawers *et al.* taught an isolated *S. typhimurium* LT2 lacking Ni-containing hydrogenase isoenzyme 2 due to a mutational defect in synthesizing the enzyme and an isolated *S. typhimurium* LT7 lacking both Ni-containing hydrogenase isoenzymes 1 and 2 due to a

mutational defect in structural genes synthesizing the enzymes. A composition comprising the cells of *S. typhimurium* is present in a phosphate buffer, i.e., a pharmaceutically acceptable carrier. See pages 398, 399 and 402; Table 1; and Discussion. Thus, the prior art *S. typhimurium* strains have 0% of respective Ni-containing hydrogenase activity. The prior art composition comprising the isolated *S. typhimurium* LT2 or LT7 inherently serves as an antigenic composition due to the presence in the cells of various protein antigens.

Claims 1-7, 18 and 20 are anticipated by Sawers *et al.*

Rejection(s) under 35 U.S.C § 103

13) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

14) Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986) as applied to claim 7 above.

The teachings of Sawers *et al.* are explained above, which do not disclose the presence of an adjuvant in their composition.

However, adding an art-known adjuvant to a prior art bacterial composition was routine and conventionally practiced in the art at the time of the invention. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an art-known adjuvant such as alum or Freund's adjuvant to the prior art *S. typhimurium* composition to produce the instant invention, since it was routine and conventional to have a bacterial

composition mixed with in an art-known adjuvant, for example, for the purpose induce antibodies to the bacterium.

Claim 8 is *prima facie* obvious over the prior art of record.

15) Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986) as applied to claim 7 above and further in view of Raettig Hansujurgen (US 3651214 A).

The teachings of Sawers *et al.* are explained above, which do not disclose that their composition is in the form of a lyophilized powder.

However, having an art-known bacterial composition produced in a lyophilized powder form for the purpose of storage was routine and conventional in the art at the time of the invention. For example, Raettig Hansujurgen taught the routine lyophilization of a composition comprising *S. typhimurium* cells in accordance with any conventional lyophilization process. See paragraph bridging columns 4 and 5.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to lyophilize Sawers' *S. typhimurium* composition into a lyophilized powder using any conventional lyophilization process as taught by Raettig Hansujurgen to produce the instant invention. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of convenient storage.

Claim 10 is *prima facie* obvious over the prior art of record.

Claim Objection(s)

16) Claim 1 is objected for the italicized limitation '*and*' in line 2 of the claim.

Claim 5 is objected for the italicized limitation '*and*' in line 4 of the claim.

Claim 6 is objected for the italicized limitation '*and*' in line 3 of the claim.

Remarks

17) Claims 1-8, 10 and 18-21 stand rejected.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

19) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

December, 2009